

C1
cont'd
than or equal to about 10 microns, said primary particles optionally being formed into agglomerates.

C2
2. (Twice amended) A pharmaceutical composition as claimed in claim 1, said [mixture] composition additionally comprising a pharmaceutically acceptable carrier, which comprises either

(a) particles having a diameter of less than about 10 microns, such that at least 50% of said [mixture] composition consists of optionally agglomerated primary particles having a diameter of less than about 10 microns; or

Sub F2
(b) coarse particles having a diameter of at least 20 microns, such that an ordered mixture is formed between the active compounds and the [said] carrier.

C3
14. (Amended) The composition of claim [11] 13, wherein said fatty acid has 10-14 carbon atoms.

C4
17. (Amended) [An] A dry powder inhaler device containing the composition of claim 1.

C5
21. (Amended) A method for systemic administration of a pharmaceutically active polypeptide, comprising providing a composition comprising a mixture of active compounds (A) a pharmaceutically active polypeptide, and (B) an enhancer compound which is a non-waxy solid at room temperature and which enhances the systemic absorption of the polypeptide in

the lower respiratory tract of a patient, said composition being in the form of a dry powder suitable for inhalation from a dry powder inhaler device; and

causing said patient to inhale said composition [; provided that the diameter of the particles of the active compounds at the point they enter the respiratory tract of the patient is less than or equal to about 10 microns] from a dry powder inhaler device; provided that at least 50% of the total mass of the active compounds, at the point the active compounds enter the respiratory tract of the patient, consists of particles having a diameter less than or equal to about 10 microns.

22. (Amended) The method of claim 21, wherein said [composition is inhaled from an inhaler device which contains said] dry powder is provided in said dry powder inhaler device in the form of agglomerates of said particles, said agglomerates being substantially deagglomerated prior to entering the respiratory tract of said patient.

Add the following new claims 33-60.

--33. A dry powder inhaler device containing the composition of claim 2.--

--34. A dry powder inhaler device containing the composition of claim 3.--

--35. A dry powder inhaler device containing the composition of claim 4.--

--36. A dry powder inhaler device containing the composition of claim 5.--

--37. A dry powder inhaler device containing the composition of claim 6.--

--38. A dry powder inhaler device containing the composition of claim 7.--

*CG
contd.* --39. A dry powder inhaler device containing the composition of claim 8.--

--40. A dry powder inhaler device containing the composition of claim 9.--

--41. A dry powder inhaler device containing the composition of claim 10.--

--42. A dry powder inhaler device containing the composition of claim 11.--

--43. A dry powder inhaler device containing the composition of claim 12.--

--44. A dry powder inhaler device containing the composition of claim 13.--

--45. A dry powder inhaler device containing the composition of claim 14.--

--46. A dry powder inhaler device containing the composition of claim 15.--

CG
cont'd
--47. A dry powder inhaler device containing the composition of claim 16.--

--48. A dry powder inhaler device containing the composition of claim 31.--

--49. A dry powder inhaler device containing the composition of claim 32.--

Sub 50
--50. The method of claim 21, wherein said polypeptide is a growth factor, interleukin, polypeptide vaccine, enzyme, endorphin, glycoprotein, lipoprotein, or polypeptide involved in the blood coagulation cascade, that exerts its pharmacological effect systemically.--

--51. The method of claim 21, wherein said polypeptide has a molecular weight of less than 30 kD.--

--52. The method of claim 21, wherein said polypeptide has a molecular weight of less than 25 kD.--

--53. The method of claim 21, wherein said polypeptide has a molecular weight of less than 20 kD.--

--54. The method of claim 21, wherein said polypeptide has a molecular weight of less than 15 kD.--

--55. The method of claim 21, wherein said polypeptide has a molecular weight of less than 10 kD.--

CS
cont'd.
Sub F7
--56. The method of claim 21, wherein said surfactant is a bile salt, a bile salt derivative, an alkyl glycoside, a cyclodextrin or derivative thereof, or a phospholipid.--

--57. The method of claim 29, wherein said fatty acid has 10-14 carbon atoms.--

--58. The method of claim 29, wherein said fatty acid is capric acid.--

Sub F7
--59. The method of claim 21, wherein said enhancer compound is a bile salt.--

--60. The method of claim 59, wherein said bile salt is sodium taurocholate.--